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PATENT

REMARKS

In the Office Action dated July 12, 2007, claims 3 to 18 are pending of which claims 3 to 18 were rejected.

In particular:

- Claims 3 to 5, 11, 13, 14 and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4634420 (Spinosa) in view of US Patent 4314560 (Helfgott et al).
- Claims 6, 8 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of US Patent 4314560 (Helfgott et al) and in view of US Patent 5160319 (Emery).
- Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of Emery and further in view of US Patent 6273877 (West).
- Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of US Patent 6018676 (Davis).
- Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of US Patent 5533986 (Mottola).
- Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of US Patent 3561596 (Knox).
- Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Emery and further in view of Davis.

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## CLAIM AMENDMENTS

Claim 3 is cancelled.

Claim 4 is amended to include the subject matters of claims 6 and 8 and claims 6 and 8 have been cancelled.

Claim 4 is also amended to define the needle lumen between the aspiration cannula and the outer needle. Support for the amendment can be found on page 9.

The dependencies of claims 7 and 9 have been amended.

Claim 10 is amended to re-introduce wording which was in the claim as lodged but appears to have been lost during some previous amendment.

We submit that in making these amendments no new subject matter has been introduced.

## DISCUSSION

Claims 3 to 5, 11, 13, 14 and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4634420 (Spinosa) in view of US Patent 4314560 (Helfgott et al).

The rejection of Claim 3 is rendered moot by the cancellation of this claim.

As we have discussed in our previous responses both the references Spinosa and Helfgott disclose an apparatus and method for the removal of tissue from an animal and the particular example is for removal of unwanted organic tissue in the eye.

The instrument disclosed in Spinosa includes a needle (14) in Figure 1 which is surrounded by a sheath (42). The needle is vibrated by an ultrasonic generator in a handle of the device, the material of the tissue is fragmented by

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vibration of the needle (column 8 lines 54 – 55) and aspiration of the fragmented tissue occurs through the needle.

The instrument of Helfgott is described as a powered hand piece for endophthalmic surgery of the eye. The device has an outer tubular member and an inner tubular coaxial member slidably received within the outer tubular member for linear reciprocation therein (column 6 lines 9 to 14). The outer tubular member has a closed end and a side aperture past which the inner tubular coaxial member slides to sever and remove pieces of vitreous tissue. It is noted, too, that there is no lumen between the inner and outer tubular members. There is also no flushing fluid supply, only an aspiration line. The outer needle also has a closed off end and a side port.

The construction of these two devices is quite different than the construction of the oocyte collection aspiration and flushing needle assembly of the present invention and these referenced devices are used for a quite different purpose. We refer the Examiner to the affidavit made by Dr. John Allan which was lodged earlier in relation to this patent application. Dr. John Allan is a reproductive medicine surgeon practising at the Wesley Reproductive Medicine & Gynaecological Surgery Unit of The Wesley Hospital, 451 Coronation Drive, Auchenflower Queensland, Australia. He is a physician who is experienced in the use of aspiration needles for the retrieval of oocytes from the ovaries of a patient. Dr Allan indicates that he has reviewed both the specification of the present invention and the reference Spinoso (US Patent 4634420). He is of the opinion that the device of Spinoso is of such a different construction and operated in a substantially different manner for its purpose of pulverizing eye tissue that the Spinoso device could not be used for the retrieval of oocytes from the ovaries of a patient. He is also of the opinion that the vibration facility of Spinoso would terminally damage an oocyte. He also discusses the importance of being able to separate the device for cleaning and checking purposes and notes that the Spinoso device does not have any arrangement for

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connecting and separating and as such again would not be useful for the retrieval of oocytes from the ovaries of a patient. We submit that although he did not review the reference Helfgott the same conclusions would have been arrived at because it has the same features of vibration to break up a mass of tissue to remove it.

In each case the devices of Spinosa and Helfgott are intended to destroy tissue within the eye of a patient by pulverisation so that it can be removed as a pulp.

In contra-distinction the present invention is directed to a device which is used to remove oocytes or eggs from one of the ovaries of a patient. Oocytes are extremely susceptible to damage during removal and hence must be extremely carefully handled during the extraction procedure as is discussed in the preamble to the specification. For this reason the two main components are separable so that there are no internal obstructions and that a physician can ensure that the components are clean. There is no relative movement between the inner and outer needles during use because such movement may cause damage to the oocytes.

Clearly, one interested in developing an apparatus for the delicate act of oocyte or egg removal would not be motivated to look toward devices for pulverizing unwanted tissue for design suggestions.

It is our submission and as indicated above the opinion of Dr. Allan that neither of the devices of Spinosa and Helfgott would be considered by the physician wishing to extract oocytes from an ovary because too much damage would result to the oocytes. Helfgott in particular does not even have an open end to the outer needle so that the only material which could be aspirated would be a slush through the side aperture.

It is further noted in Spinosa that the needle 14 has a base 56 which is permanently connected into housing 41 by the lugs 47 in the housing fitting into

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the groove in the base 56. Although the device is shown in an exploded view in Figure 1, it is clearly not intended that the two components, the housing 41 and sheath 42 and the needle assembly 12 be supplied as separate components to the physician to be connected. There is no connection arrangement shown or taught in Spinoso by which a user and particularly a user wearing surgical gloves in a operating theatre, could disconnect and re-connect the two components. They are supplied connected.

The examiner has referred us to "a first connector portion 47 on the handle and a second connector portion 58 on the aspiration cannula". The item 47 is a continuous annular ring and the item 58 is a threaded portion to connect to a motorised handpiece. These are not intended or illustrated as being connected together. If it was that the examiner intended to refer to the continuous annular ring 47 and the continuous groove 66 on the needle 12 this is still not the same as that disclosed and claimed on the present invention. The needle of Spinoso is "snapped" into the handle (column 12 line 13) and clearly is not intended to be removed. As is described in column 12 lines 12 to 15:

"and will remain fixed thereon in a sealing fit so that fluid will not pass therefrom nor will the sheath move from the needle. "

As discussed on page 7 lines 19 to 24 of the present application, it is advantageous to supply the aspiration assembly in a dissembled state so that a surgeon or physician can be satisfied that all the components are clean and ready to use before assembling them. This is clearly not possible in Spinoso as the needle would be supplied in the assembly as shown in Figure 2. There is no mechanism provided or suggested which would enable a user to join or separate the two components of Spinoso. As we have discussed before the exploded view of Figure 1 is not indication of how it would be supplied or used. For these reasons we submit that the examiner is not correct in her statement in

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paragraph 4 of the Detailed Office Action because Spinosa does not disclose "a separable flushing and aspiration needle".

The examiner has specifically stated that the "device of Spinosa is capable of aspirating an oocyte". With respect, we submit that this is absolutely wrong and incorrect. On oocyte is an extremely delicate and fragile item and cannot take passing around sharp corners or restrictions. The teaching of Spinosa as to the configuration of the tip of the Spinosa needle is given in column 3 lines 35 to 40. The operative end has an end wall and an opening either in the end wall or at the side of the end wall. This configuration is shown Figures 4 and 5 where the access to the lumen 60 of the needle is via a small aperture 61 or 62. The device of Spinosa is not capable of aspirating an oocyte.

For these further reasons we submit that neither Spinosa and Helfgott teach or suggest the claimed invention and that claims 4 to 5, 11, 13, 14 and 15 are patentable over these reference taken either separately or in combination.

The rejection of claims 6 and 8 is rendered moot by the cancellation of these claims.

Claim 9 was rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of US Patent 4314560 (Helfgott et al) and in view of US Patent 5160319 (Emery) but as this claim depends from an inventive claim 4 as discussed above, we submit that this claim, too, is inventive.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of Emery and further in view of US Patent 6273877 (West). Claim 7 specifies that the "the bevelled tip is *further sharpened* with a secondary bevel to assist with cutting into a follicle. The teaching of West is that a secondary bevel is placed onto the tip of an epidural needle to provide "an adequate degree of blunting to prevent inadvertent damage to the dura matter" (Column 4 lines 42 - 43). The secondary bevel is

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placed to make the needle blunt rather than to sharpen it as defined in the present claims. Further we submit as this claim depends from an inventive claim 4 as discussed above, we submit that this claim, too, is inventive.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of US Patent 6018676 (Davis) but as this claim depends from an inventive claim 4 as discussed above, we submit that this claim, too, is inventive. We further note, however, that Davis teaches the echogenicity can be obtained by placement of certain patternings on a stylet which is within a cannula. This is different than in the present invention where the outer needle has the treatment.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of US Patent 5533986 (Mottola) but as this claim depends from an inventive claim 4 as discussed above, we submit that this claim, too, is inventive.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott et al in view of US Patent 3561596 (Knox) but as these claims all depend from an inventive claim 4 as discussed above, we submit that these claims, too, are inventive.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Emery and further in view of Davis. For the reasons as discussed above in relation to claim 4 we submit that this claim, too, is inventive. We further note, however, that Davis teaches the echogenicity can be obtained by placement of certain patternings on a stylet which is within a cannula. This is different than in the present invention where the outer needle has the treatment.

The re-examination and reconsideration of this application is respectfully requested and it is further requested this application be passed to issue.

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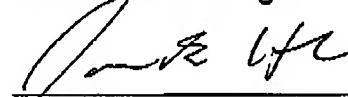
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Although the foregoing discussion is believed to be disposed of the issues in this case, applicant's attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment and remarks.

Date: 10 October 2007

Respectfully,

Michael Carl Junger



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